510(k) Summary

JUL 1 8 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information

Date Prepared:	April 24, 2013
Submitter's Name & Address:	Thoratec Corporation 23 4th Avenue Burlington, MA 01803
Contact Person:	Yverre Bobay Sr. Manager, Regulatory Affairs Ph: 781-852-8276 Fax: 781-852-0139 Thoratec Corporation 23 4th Avenue Burlington, MA 01803

B. Device Information

Trade or Proprietary Name:	1. 2nd Generation CentriMag® Primary Console 2. Mag Monitor
Common or Usual Name:	Cardiopulmonary Bypass Pump Console
Classification Name:	Class II, DWA, 21 CFR – 870.4380 Control, Pump Speed, Cardiopulmonary Bypass
Performance Standard:	Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Legally Marketed Predicate Devices

- CentriMag System (K020271)
- 2nd Generation CentriMag Primary Console and Mag Monitor (K102129)

D. Device Description

- **2nd Generation CentriMag Primary Console**

  The 2nd Generation CentriMag Primary Console is a microprocessor based device. The microprocessor generates the primary motor control signal, monitors system sensors, generates display outputs, interprets the inputs through the front keypad, provides alarm functions and handles the Mag Monitor interface. The Console is intended to be operated on single phase AC power; however, it also has a built-in rechargeable battery with a battery charger. The rechargeable battery is field replaceable. In addition, an optional external modular battery (UPS) can be used to power the CentriMag Primary Console. The human interface of the CentriMag Primary Console consists of a graphical screen to display data and system options and touch pads to change the system status. The 2nd Generation CentriMag Primary Console is intended to be used together with the Mag Monitor; however it can be also operated as a stand-alone unit.

- **Mag Monitor**

  The Mag Monitor provides a redundant user interface containing a display and touch pads. The Mag Monitor is a non-sterile, reusable device that is designed to work only with the 2nd Generation CentriMag Primary Console. The Mag Monitor is a 12V DC-powered device and receives its power directly from 2nd Generation CentriMag Primary Console via a power connector that mates with a connector on the back-panel of 2nd Generation CentriMag Primary Console. Based on the design of its power connector, the Mag Monitor cannot be plugged into a hospital AC power outlet. The Mag Monitor's core function is to provide multi-color alpha-numerical and graphical displays of information it receives from the 2nd Generation CentriMag Primary Console.

  The Mag Monitor is a processor based device, with a flat color screen (e.g. LCD). In addition, it is equipped with touch pad to allow the user to enter commands. In the hospital-setting configuration, the user is able to operate and monitor the performance of the CentriMag System through the Monitor. The Monitor can control the functions of the 2nd Generation CentriMag Primary Console, and therefore, of the CentriMag System. The Monitor only displays data and stores user commands without interacting directly with the primary motor control which is managed by the 2nd Generation CentriMag Primary Console. The Mag Monitor is connected to the 2nd Generation CentriMag Primary Console through one cable, which includes data and power lines. Power is provided by the 2nd Generation CentriMag Primary Console.

  The redesigned Mag Monitor is compatible with both the current 2nd Generation Console and the redesigned 2nd Generation Console. However, when plugged into the current Console, the redesigned Mag Monitor will only operate when the Console is connected to AC power. It will not operate when the current Console is run on Battery power

E. Intended Use

The 2nd Generation CentriMag Primary Console and Mag Monitor are indicated for use with the CentriMag Blood Pump.

The CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The technological characteristics of the 2nd Generation CentriMag Primary Console and the Mag Monitor are the same as the predicate devices.

G. Comparison to Predicate Device

The 2nd Generation CentriMag Primary Console and the Mag Monitor have an indication for use, design features, and functional characteristics which are substantially equivalent to the predicate devices. Due to the equivalency of indications for use, design features, and functional characteristics, these devices raise no new safety or effectiveness issues.

H. Summary of Performance Data

The 2nd Generation CentriMag Primary Console and the Mag Monitor have successfully undergone functional testing demonstrating substantial equivalence to the predicate devices.

The following performance tests have been conducted on the redesigned 2nd Generation and Mag Monitor with successful results:

- System-Software Verification
- Functional Safety Review
- Basic Electrical Safety
- Environmental Test
- Surface Cleaning
- EMC
- Reliability
- Transportation
- Rough Handling Test - Drop
- Rough Handling Test - Shock
- Rough Handling Test - Vibration
- Drip Proof
- Electrosurgical Unit (ESU) Interference
- Battery Run Time Test using Blood Analog

- Airborne Equipment Test according to RTCA DO-160F

The risk management methods used to assess the operational integrity of the 2nd Generation CentriMag Primary Console and the Mag Monitor were a Risk Analysis and a Failure Modes and Effects Analysis (FMEA).

I. Clinical Performance

Clinical testing was not performed.

J. Conclusion

The redesigned 2nd Generation CentriMag Primary Console and the Mag Monitor are substantially equivalent to the current 2nd Generation CentriMag Primary Console and Mag Monitor (K102129) and the CentriMag System (K020271).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

Thoratec Corporation
Yverre Bobay
23 4th Avenue
Burlington, MA 01803

Re: K131179
Trade/Device Name: 2nd Generation CentriMag Primary Console; Mag Monitor
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA
Dated: June 5, 2013
Received: June 7, 2013

Dear Yverre Bobay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: **Thoratec Corporation**

510(k) Number (if known): K131179

Device Name: **CentriMag 2nd Generation Primary Console & Mag Monitor**

Indications for Use:

The 2nd Generation CentriMag Primary Console and Mag Monitor are indicated for use with the CentriMag Extracorporeal Blood Pumping System. The CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use X OR Over-the Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)